

Remarks

Claims 54-61, 64, and 67-69 are pending in the application. Claims 1-53, 62-63, and 65-66 have been cancelled; and claims 54-61 and 64 have been amended. No new matter has been added and Applicant respectfully submits that the claim amendments do not raise any new issues. In this regard, claim 64, the sole remaining independent claim, has been amended to include the features of canceled claims 52, 65, and 66. In light of the Final Office Action, Applicant believes these amendments and cancellations serve a useful clarification purpose, and are desirable for clarification purposes, independent of patentability. Accordingly, Applicant respectfully submits that the claim amendments do not limit the range of any permissible equivalents.

35 U.S.C. §102 Claim Rejections

Claims 52 and 56-62 were rejected under 35 U.S.C. §102(b) as being anticipated by Schwartz *et al.* (“Schwartz”). Claim 52, the sole independent claim rejected as anticipated by Schwartz, has been cancelled, rendering the rejection moot. Accordingly, Applicant respectfully submits that this rejection should be withdrawn.

35 U.S.C. §103 Claim Rejections

Claim 53 was rejected under 35 U.S.C. §103(a) as being unpatentable over Schwartz in view of Mitchell *et al.* (5288711) (“Mitchell”). Claim 54 was rejected under 35 U.S.C. §103(a) as being unpatentable over Schwartz in view of Stinson (5980564). Claim 55 was rejected under 35 U.S.C. §103(a) as being unpatentable over Schwartz in view of Liprie *et al.* (6491662). Claims 63-69 were rejected under 35 U.S.C. §103(a) as being unpatentable over Schwartz in view of Sukhatme (2005/261283) (“Sukhatme”). For the reasons stated below, Applicant respectfully submits that these rejections should be withdrawn.

Initially, Applicant notes that claim 53 has been cancelled. Furthermore, the remaining rejected claims have been amended to depend from claim 64. Thus, Schwartz, Sukhatme, and their combination are primarily discussed.

Schwartz discloses a radially expandable stent for implantation within a body lumen.. (Abstract). ..a flexible or elastomeric polymeric film..extends between the metal elements. (Col. 3, lns. 59-60). ..the stent may also incorporate therapeutic substances in or on the polymeric film.. (Col. 3, lns. 66-68). With reference to Fig. 10 of Schwartz, a zig-zag stent wire 42 is formed and a polymeric film 45 is formed on the wire 42 by application of a urethane in a solvent.. (Col. 6, lns. 40-43). ..various therapeutic substances can be incorporated in or applied to the polymeric film to provide such substances to the blood or to the lumen wall. (Col. 7, lns. 1-4). Application of the therapeutic substance to the film can include applying it on the surface of the film or incorporating it into the film as it is made. (Col. 7, lns. 14-17). For example, microcapsules can be used to carry the therapeutic substance either in or on the film and to provide timed-release of the substance to the blood or to the blood vessel or both. (Id).

Schwartz thus does not disclose or suggest the use of a stent that is made of a plurality of stent preforms, with each of the stent preforms comprising a metallic core with an outer sheath totally encapsulating the core.

Sukhatme also does not contain any such teaching or suggestion. In particular, Sukhatme relates to methods and compositions for the treatment of graft failure. Sukhatme contemplates local administration of the therapeutic agents via drug delivery systems such as stents, microsphere, drug loaded film, suture, composite system, or microspheres in film. (§ 234-235). However, Sukhatme, contains nothing that teaches or suggests a plurality of stent preforms, with each of the stent preforms comprising a metallic core with an outer sheath totally encapsulating the core.

In contrast, the present invention discloses, with reference to Fig. 8, ..a therapeutically coated stent preform 10 [including] an intravascular implant with takes the form of a wire or core 12 with a contact surface 14 and core ends 16 and 18. (§[0130]). ..the present invention relates to a combinatorial therapy for delivery of more than one agent through a coating on any

intravascular implant. (¶[0110]). The intravascular implant may be, but is not limited to, a balloon catheter, stent, stent graft, drug delivery catheter, atherectomy device, filter, scaffolding device, anastomotic clip, anastomotic bridge, suture material, metallic or non-metallic wire, embolic coil or a combination thereof. (Id).

Suitable polymers for this application include biocompatible polymers of particular permeability. (¶[0133]). With reference to Fig. 9 of the present invention, the sheath 20 has an interior surface 30, which closely communicates with the contact surface 14 of the core 12. (Id). In a preferred embodiment, the polymer is selected as a heat-shrinkable polymer. The sheath 20 may also be in the form of a thin film, which is deposited over the entire surface of core 12.

The outer sheath 20 may be knitted or woven to form a braided configuration, however a sheath formed in this manner must still completely encapsulate the core 12. (¶[0134]). The braided configuration is also designed to cover the ends 16 and 18 of core 12, as seen in FIG. 8. (Id).

Fig. 10 of the present invention shows the outer sheath 20 formed of several layers of material. The layers may be of the same or varying thickness, and may be the same or different materials. (¶[0135]). The top coat can delay the release of the pharmaceutical agent, or it could be used as a matrix for the delivery of a different pharmaceutically active material. (¶[0127]).

Claim 64 recites, *inter alia*, a method of treating a vascular disease of a patient with a plurality of stent preforms interlaced to form a stent, the method comprising: determining a prevalent disease process in the pathology of the vascular disease; selecting the therapeutic agent to treat or prevent the prevalent disease process, the plurality of stent preforms including the therapeutic agent; and implanting the stent in the patient to treat the vascular disease, wherein each of the plurality of stent preforms comprises: an elongated metallic core including a contact surface and first and second ends; an outer sheath disposed about the contact surface of the core, the outer sheath including the therapeutic agent; and caps disposed on the ends of the outer sheath thereby encapsulating the first and second end of the core.

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Accordingly, Applicant respectfully submits that claim 64 is patentable over Schwartz, and Schwartz in view of Sukhatme. As claims 54-61, and 67-69 depend from claim 64, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the cited references at least for the same reasons.


In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 103 rejections.

Conclusion

In the light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fee is believed to be due. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 503410 (Docket No. 795-A03-004).

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Pce DR", with a long horizontal stroke extending to the right.

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